

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in March 2016.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-392

Trade Name: Imrestor™
Ingredients: Pegbovigrastim
Sponsor: Elanco Animal Health, A Division of Eli Lilly & Co.
Approval Date: March 11, 2016
Status: Rx
Route: Subcutaneous injection
Species: Periparturient dairy cows and periparturient replacement dairy heifers
Drug Form: Injectable solution
Concentration: 15 mg pegbovigrastim per 2.7 mL syringe
Indications: For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.
Exclusivity: 5 years

NADA Number: 141-455

Trade Name: GALLIPRANT®
Ingredients: Grapiprant
Sponsor: Aratana Therapeutics, Inc.
Approval Date: March 20, 2016
Status: Rx
Route: Oral
Species: Dogs
Drug Form: Tablets
Concentration: 20 mg, 60 mg, or 100 mg
Indications: For the control of pain and inflammation associated with osteoarthritis in dogs.
Exclusivity: 5 years
Patent: Patent Number Expiration date:
6,710,054 October 15, 2021
7,960,407 March 1, 2026

NADA Number: 141-460

Trade Name: Aivlosin® 17%
Ingredients: Tylvalosin
Sponsor: ECO LLC
Approval Date: March 24, 2016
Status: VFD
Route: Oral, in feed
Species: Swine
Drug Form: Type A medicated article
Concentration: Tylvalosin 17% w/w (77.12 g tylvalosin/lb, equivalent to tylvalosin tartrate 19.4% w/w)
Indications: For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.
Exclusivity: 3 years

Sponsor Change

(A)NADA Numbers: 200-069, 200-253, 099-169, 124-241

Previous Sponsor: Bayer HealthCare LLC, Animal Health Division

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New Sponsor: Cross Vetpharm Group Ltd.

Drug Labeler Code: 061623

Sponsor Name Change

Previous Name: Huvepharma AD

New Name: Huvepharma EOOD

Patent Extensions

NADA Number: 141-334

Patent number: 6,514,946

Extension Period: 1,482 days

Expiration Date: September 10, 2024